

REMARKS

In view of the above amendments and following remarks, applicants request an early and favorable Action.

Discussion of the Amendments

In his September 9, 2004 Action, the Examiner noted that he found applicants' arguments, submitted in a September 16, 2003 Request for Reconsideration of Examiner's Requirement for Restriction, to be persuasive respecting rejoining Groups II and III but not with respect to rejoining Group I with either group. Accordingly, applicants have amended Claims 1 and 19, previously generic to all groups, to read more particularly on the subject matter of Groups II and III. Support for the amendment to Claim 1 is found in Claim 6 (now cancelled) as filed originally. Claim 19 was simply amended to refer to Claim 18 only instead of Claims 16, 17, and 18

Support for the amendment to Claim 18 may also be found in Claim 6 as filed originally.

Claims 7 to 9, 14, and 15 were amended to depend from Claim 1 as Claim 1 now defines the subject matter of Claim 6 (now cancelled) from which these claims previously depended.

Claim 6 has been cancelled.

The presently pending elected claims are Claims 1, 7 to 11, 14, 15, 18, and 19.

Discussion of the Examiner's Section 102(e) Rejection  
of Claims 1, 7 to 11, 14, 15, 18, and 19 as Being Anticipated by Monahan et al.

The Examiner rejected Claims 1, 7 to 11, 14, 15, 18, and 19 under Section 102(e) as being anticipated by U.S. Patent No. 6,379,966 to Monahan et al.

The Examiner's rejection is traversed respectfully.

Claim 1, from which Claims 7 to 11, 14, and 15 depend, recites the step of modifying a DNA complex by reacting cationic head groups of the cationic lipids or polymers therein with a reagent that reacts therewith to neutralize the positive charge thereon. Claim 18, of which Claim 19 includes the recitations thereof, recites a colloid comprising a DNA complex in which the cationic head groups of the cationic lipids or polymers therein are modified with a reagent that reacts therewith to neutralize the positive charge thereon.

Monahan et al. does not disclose a DNA complex in which cationic head groups are combined with a reagent that neutralizes the positive charge of the head groups. In contrast, Monahan et al. (see quote from column 23 thereof recited on page 7 of the Action) discloses a three-layer complex comprising DNA, a polycation layer and a polyanion layer. Monahan et al. does not elaborate on how this three-layer complex is formed nor is there any disclosure of reacting a reagent with the cationic head groups of the polycation as required in applicants' invention. Rather, it appears that polyanions are added to bind electrostatically with the polycations (as opposed to a reagent reacting with a polycation).

The Examiner cited column 25, lines 27 to 36, of Monahan et al. which disclose the use of citraconic anhydride (a reagent) to react with poly-L-lysine (a polycation) to form in making citraconylpoly-L-lysine. The citraconylpoly-L-lysine

then is mixed with a polycation-DNA complex to form an anionic particle. Monahan et al. uses a reagent to modify a polycation and then mixes the modified polycation with polycation-DNA complexes. This is a completely different from applicants' invention wherein a reagent is reacted with a polycation which is already present in the polycation-DNA complex.

Given the above, it is apparent that Monahan et al. discloses a completely different development from applicants' invention. As such Monahan et al. does not anticipate applicants' claims.

Discussion of the Examiner's Section 103(a) Rejection  
of Claims 1, 7 to 11, 14, 15, 18, and 19 as Being Obvious Over Monahan et al.

The Examiner rejected Claims 1, 7 to 11, 14, 15, 18, and 19 as being obvious over Monahan et al. This rejection is traversed respectfully.

As stated above, Monahan et al. does not teach the use of a reagent which modifies a polycation-DNA complex by reacting with the cationic head groups thereof. The Examiner's rejection was based on a misinterpretation of Monahan et al. Given that the Examiner has failed to show how Monahan et al. otherwise teaches or suggests the use of a reagent to modify a polycation-DNA complex, the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the cited reference or references must teach or suggest all of the elements of the claim. M.P.E.P. §2143.03.

Discussion of the Examiner's §102(e)  
Rejection of Claim 1 Over Semple et al.

The Examiner rejected Claim 1 as being anticipated by U.S. Patent No. 6,287,591 to Semple et al.

The Examiner's rejection is traversed respectfully. As stated above, Claim 1 recites the use of a reagent to react with the cationic head groups of the cationic polymers or lipids in a DNA-containing complex. There is no disclosure at all in Semple et al. respecting the use of such a reagent. Rather, Semple et al. discloses a lipid-DNA complex in which the charge of the lipid changes depending upon the pH of the surrounding medium (see column 9 of Semple et al.).

As Semple et al. fails to disclose the subject matter of Claim 1, the Examiner's rejection of Claim 1 as being anticipated thereby is traversed respectfully.

Discussion of the Examiner's Section 103(a)  
Rejection of Claims 1, 7 to 11, 14, 18, and 19 As Being  
Unpatentable Over Semple et al. in view of Trubetskoy et al. and Monahan et al.

The Examiner rejected Claims 1, 7 to 11, 14, 18, and 19 under Section 103(a) as being unpatentable over U.S. Patent No. 6,287,591 to Semple et al. in view of U.S. Patent Application Publication No. 2003/0026841 to Trubetskoy et al. and U.S. Patent No. 6,379,966 to Monahan et al. The Examiner cited Semple et al. for disclosing generally the modification of DNA-polycation complexes so that they have a net neutral charge, Trubetskoy et al. for disclosing the use of a recharging process to modify DNA-polycation complexes, and Monahan et al. for disclosing the use of a reagent in the recharging process.

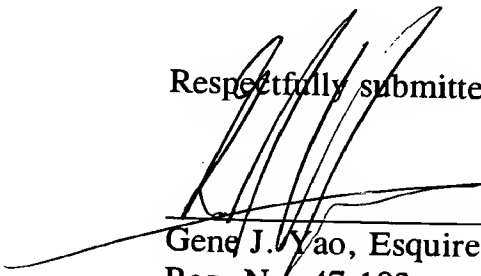
The Examiner's rejection is traversed respectfully. As stated above, Monahan et al. fails to disclose the use of a reagent which reacts with the cationic head groups of a polycation in a polycation-DNA complex. Semple et al. and Trubetskoy et al. do not remedy this deficiency. As such, the combined references do not teach or suggest each of the elements of the rejected claims. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the cited reference or references must teach or suggest all of the elements of the claim. M.P.E.P. §2143.

#### Conclusion

In view of the foregoing, an early and favorable Action is requested respectfully.

This Request is accompanied by a Petition for Extension of Time to respond to the Examiner's Action.

Respectfully submitted,



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